Neurocrine Biosciences Presents New KINECT® 4 Post-Hoc Analysis Demonstrating Rapid and Sustained Therapeutic Efficacy of INGREZZA® (valbenazine) 40 mg Capsules

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- Continuous treatment with INGREZZA 40 mg for 48 weeks resulted in sustained, clinically meaningful improvements in tardive dyskinesia symptoms
- 90% of participants who completed 48 weeks of continuous treatment with INGREZZA 40 mg achieved a ≥50% improvement in the Abnormal Involuntary Movement Scale Total Score
- INGREZZA is the only vesicular monoamine transporter 2 (VMAT2) inhibitor that allows patients to start immediately at a therapeutic dose without required titration

SAN DIEGO, Oct. 17, 2025 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced the presentation of a new post-hoc analysis from the Phase 3, open-label KINECT® 4 study, demonstrating that patients treated continuously for 48 weeks with the 40 mg dose of once-daily INGREZZA® (valbenazine) capsules experienced clinically meaningful improvements in tardive dyskinesia symptoms. Findings will be presented at the American Psychiatric Nurses Association 39th Annual Conference, taking place October 15-18 in New Orleans.

"The KINECT 4 post-hoc analysis demonstrated the rapid, sustained, long-term clinical benefit of treatment with INGREZZA at the lowest available dose of 40 mg," said Sanjay Keswani, M.D., Chief Medical Officer, Neurocrine Biosciences. "INGREZZA is the only VMAT2 inhibitor that allows patients to start at a therapeutic dose, stay at that dose or adjust to 60 mg or 80 mg, based on individual response and tolerability. These findings add to previously published data supporting 40 mg as an effective, long-term treatment option."

The KINECT 4 Phase 3, open-label study evaluated the long-term efficacy, safety and tolerability of INGREZZA in adults with tardive dyskinesia (TD). Participants in the post-hoc analysis received INGREZZA 40 mg once daily for the first four weeks, with the option to escalate to 80 mg daily at Week 4, based on tolerability and clinical response. From Week 4 through Week 48, dose reduction from 80 mg to 40 mg was permitted based on individual tolerability.

This analysis included patients in the INGREZZA 40 mg group (n=45), who received 40 mg throughout the entire study, as well as patients in the INGREZZA 80/40 mg group (n=11), who increased to 80 mg at Week 4 and subsequently reduced to 40 mg. Efficacy was evaluated at all post-baseline visits through end of treatment (Week 48) using clinician- and patient-reported changes in TD severity, as measured by the Abnormal Involuntary Movement Scale (AIMS), Clinical Global Impression of Change-TD (CGI-TD) and Patient Global Impression of Change (PGIC).

Efficacy outcomes demonstrated that clinically meaningful improvements in TD were sustained throughout the 48-week treatment period in both the INGREZZA 40 mg and INGREZZA 80/40 mg groups:

- At all post-baseline visits (Week 4 to Week 48), the mean change from baseline in AIMS total score exceeded the minimally clinical important difference threshold, demonstrating rapid and continuous improvements with INGREZZA treatment.
- Among those who received 40 mg throughout the entire study, the percentage of participants meeting the AIMS response threshold (≥50% total score improvement from baseline) generally increased over time, with 90% (18/20) of those completing 48 weeks reaching this threshold.
- The analysis also showed that patients who reduced their dose from 80 mg to 40 mg for tolerability reasons achieved similar therapeutic benefits.
- From Week 8 through Week 48, more than half of all participants across both treatment groups met the response threshold for CGI-TD and PGIC, with 90% (18/20) of participants on continuous INGREZZA 40 mg treatment being "much improved" or "very much improved" at Week 48 per clinician assessment (CGI-TD) and patient self-report (PGIC).
- Efficacy outcomes with INGREZZA 40 mg were comparable to those achieved with 80 mg in the original KINECT 4 study.

In the study, safety and tolerability of treatment was consistent with the known profile of INGREZZA with no new concerns identified, and most treatment-emergent adverse events were mild or moderate in intensity. The most common side effects of INGREZZA in people with TD are sleepiness and tiredness.

Additional presentations at the American Psychiatric Nurses Association 39th Annual Conference:

- Physical, Mental, and Socioemotional Functional Improvement Following Valbenazine Treatment for TD: A Case Series
- Estimation of the Minimal Clinically Important Difference and Longitudinal Change in the Tardive Dyskinesia Impact Scale, a Validated, Tardive Dyskinesia-Specific, Patient-Reported Outcome Measure
- Once-Daily Valbenazine Improves the Impacts and Symptoms of Tardive Dyskinesia in Patients: Results From the Phase 4 KINECT-PRO Study
- Valbenazine Improves Physical, Social, and Emotional Impacts on the Tardive Dyskinesia Impact Scale (TDIS): Post Hoc Analyses of KINECT-PRO Data

About Tardive Dyskinesia
Tardive dyskinesia (TD) is a movement disorder that is characterized by uncontrolled, abnormal and repetitive movements of the face, torso and/or other body parts, which may be disruptive and negatively impact patients. The condition is associated with taking certain kinds of mental health medicines (antipsychotics) that help control dopamine receptors in the brain. Taking antipsychotics commonly prescribed to treat mental illnesses such as major depressive disorder, bipolar disorder, schizophrenia and schizoaffective disorder and other prescription medicines (metoclopramide and prochlorperazine) used to treat gastrointestinal disorders are associated with TD. In patients with TD, these treatments are thought to result in irregular dopamine signaling in a region of the brain that controls movement. The symptoms of TD can be mild to severe and are often persistent and irreversible. TD is estimated to affect at least 800,000 adults in the U.S.

About the KINECT 4 Phase 3 Study
KINECT 4 is a Phase 3, open-label study in which 163 participants with moderate to severe TD and underlying schizophrenia, schizoaffective disorder or mood disorder (including bipolar disorder or major depressive disorder) received 48 weeks of open-label treatment with once-daily INGREZZA (40 mg or 80 mg capsules) followed by a four-week washout. Dosing was initiated at 40 mg/day in all participants, with escalation to 80 mg/day at Week 4 based on effectiveness and tolerability. Dose reduction to 40 mg was allowed in participants who could not tolerate the 80 mg dose. Patients were discontinued if the new dose was not tolerated.

Participants experienced TD improvements during long-term treatment as demonstrated by mean change from baseline to Week 48 in AIMS total score (sum of items 1-7, evaluated by site raters) with INGREZZA 40 mg/day (-10.2) or 80 mg/day (-11.0). Consistent with previous studies, INGREZZA was generally well tolerated. After Week 4, treatment-emergent adverse events that occurred in ≥5% of all participants (combined dose groups) were urinary tract infection (8.5%) and headache (5.2%). Changes from baseline in psychiatric stability, vital signs, electrocardiogram parameters and laboratory test values were generally small and not clinically significant.

About INGREZZA ® (valbenazine) Capsules and INGREZZA® SPRINKLE (valbenazine) Capsules
INGREZZA is a selective vesicular monoamine transporter 2 (VMAT2) inhibitor approved by the U.S. Food and Drug Administration for the treatment of adults with tardive dyskinesia and the treatment of chorea associated with Huntington's disease (HD). Only INGREZZA offers a therapeutic dose from day one with no required titration.

INGREZZA, developed by Neurocrine Biosciences, selectively inhibits VMAT2 with no appreciable binding affinity for VMAT1, dopaminergic (including D2), serotonergic, adrenergic, histaminergic or muscarinic receptors. While the specific way INGREZZA works to treat TD and HD chorea is not fully understood, INGREZZA is unique in that it selectively and specifically targets VMAT2 to inhibit the release of dopamine, a chemical in the brain that helps control movement. INGREZZA is believed to reduce extra dopamine signaling, which may lead to fewer uncontrollable movements.

INGREZZA is studied across the widest range of patients. It is always one capsule, once daily and can be taken together with most stable mental health regimens such as antipsychotics or antidepressants. Only INGREZZA offers the benefit of a sprinkle formulation, INGREZZA SPRINKLE, for those who experience dysphagia, have difficulty swallowing or prefer not to swallow a pill. INGREZZA and INGREZZA SPRINKLE dosages approved for use are 40 mg, 60 mg and 80 mg capsules.

Important Information
Approved Uses
INGREZZA® (valbenazine) capsules or INGREZZA® SPRINKLE (valbenazine) capsules are prescription medicines used to treat adults with:

- movements in the face, tongue, or other body parts that cannot be controlled (tardive dyskinesia).
- involuntary movements (chorea) of Huntington's disease. INGREZZA or INGREZZA SPRINKLE do not cure the cause of involuntary movements, and do not treat other symptoms of Huntington's disease, such as problems with thinking or emotions.

It is not known if INGREZZA or INGREZZA SPRINKLE is safe and effective in children.

IMPORTANT SAFETY INFORMATION

INGREZZA or INGREZZA SPRINKLE can cause serious side effects in people with Huntington's disease, including: depression, suicidal thoughts, or suicidal actions. Tell your healthcare provider before you start taking INGREZZA or INGREZZA SPRINKLE if you have Huntington's disease and are depressed (have untreated depression or depression that is not well controlled by medicine) or have suicidal thoughts. Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is especially important when INGREZZA or INGREZZA SPRINKLE is started and when the dose is changed. Call your healthcare provider right away if you become depressed, have unusual changes in mood or behavior, or have thoughts of hurting yourself.

Do not take INGREZZA or INGREZZA SPRINKLE if you:

- are allergic to valbenazine, or any of the ingredients in INGREZZA or INGREZZA SPRINKLE.

INGREZZA or INGREZZA SPRINKLE can cause serious side effects, including:

- **Allergic reactions.** Allergic reactions, including an allergic reaction that causes sudden swelling called angioedema, can happen after taking the first dose or after many doses of INGREZZA or INGREZZA SPRINKLE. Signs and symptoms of allergic reactions and angioedema include: trouble breathing or shortness of breath, swelling of your face, lips, eyelids, tongue, or throat, or other areas of your skin, trouble with swallowing, or rash, including raised, itchy red areas on your skin (hives). Swelling in the throat can be life-threatening and can lead to death. Stop taking INGREZZA or INGREZZA SPRINKLE and go to the nearest emergency room right away if you develop these signs and symptoms of allergic reactions and angioedema.
- **Sleepiness and tiredness that could cause slow reaction times (somnolence and sedation).** Do not drive a car or operate dangerous machinery until you know how INGREZZA or INGREZZA SPRINKLE affects you. Drinking alcohol and taking other medicines may also cause sleepiness during treatment with INGREZZA or INGREZZA SPRINKLE.
- **Heart rhythm problems (QT prolongation).** INGREZZA or INGREZZA SPRINKLE may cause a heart rhythm problem known as QT prolongation. You have a higher chance of getting QT prolongation if you also take certain other medicines during treatment with INGREZZA or INGREZZA SPRINKLE. Tell your healthcare provider right away if you develop any signs or symptoms of QT prolongation, including: fast, slow, or irregular heartbeat (heart palpitations), shortness of breath, dizziness or lightheadedness, or fainting or feeling like you are going to faint.
- **Neuroleptic Malignant Syndrome (NMS).** NMS is a serious condition that can lead to death. Call a healthcare provider right away or go to the nearest emergency room if you develop these symptoms and they do not have another obvious cause: high fever, stiff muscles, problems thinking, irregular pulse or blood pressure, increased sweating, or very fast or uneven heartbeat.
- **Parkinson-like symptoms.** Symptoms include: body stiffness, drooling, trouble moving or walking, trouble keeping your balance, shaking (tremors), or falls.

Before taking INGREZZA or INGREZZA SPRINKLE, tell your healthcare provider about all of your medical conditions including if you: have liver or heart problems, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Make sure you tell all of your healthcare providers that you are taking INGREZZA or INGREZZA SPRINKLE. Taking INGREZZA or INGREZZA SPRINKLE with certain other medicines may cause serious side effects. Especially tell your healthcare provider if you: take digoxin or take or have taken a monoamine oxidase inhibitor (MAOI) medicine. You should not take INGREZZA or INGREZZA SPRINKLE if you are taking, or have stopped taking, a MAOI within the last 14 days.

The most common side effects of INGREZZA or INGREZZA SPRINKLE in people with tardive dyskinesia are sleepiness and tiredness.

The most common side effects of INGREZZA or INGREZZA SPRINKLE in people with chorea associated with Huntington's disease include sleepiness and tiredness, raised itchy red areas on your skin (hives), rash, and trouble getting to sleep or staying asleep.

These are not all of the possible side effects of INGREZZA or INGREZZA SPRINKLE. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at **www.fda.gov/medwatch** or call **1-800-FDA-1088.**

Dosage Forms and Strengths: INGREZZA and INGREZZA SPRINKLE are available in 40 mg, 60 mg, and 80 mg capsules.

Please see full Prescribing Information, including Boxed Warning, and Medication Guide.

About Neurocrine Biosciences, Inc.
Neurocrine Biosciences is a leading neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine and neuropsychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, chorea associated with Huntington's disease, classic congenital adrenal hyperplasia, endometriosis* and uterine fibroids*, as well as a robust pipeline including multiple compounds in mid- to late-phase clinical

development across our core therapeutic areas. For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders because you deserve brave science. For more information, visit neurocrine.com, and follow the company on LinkedIn, X and Facebook. (**in collaboration with AbbVie*)

Forward-Looking Statements
In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements regarding the potential benefits to be derived from INGREZZA and the value INGREZZA may bring to patients. Factors that could cause actual results to differ materially from those stated or implied in the forward-looking statements include, but are not limited to, the following: risks and uncertainties associated with Neurocrine Biosciences' business and finances in general, as well as risks and uncertainties associated with the commercialization of INGREZZA; whether INGREZZA receives adequate reimbursement from third-party payors; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA; risks associated with the Company's dependence on third parties for development and manufacturing activities related to INGREZZA, and the ability of the Company to manage these third parties; risks that additional regulatory submissions for INGREZZA or other product candidates may not occur or be submitted in a timely manner; risks that the FDA or other regulatory authorities may make adverse decisions regarding INGREZZA; risks that post-approval INGREZZA commitments or requirements may be delayed; risks that INGREZZA may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2025. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof other than required by law.

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SOURCE Neurocrine Biosciences, Inc.

Media: Aimee White, 1-858-354-7865, media@neurocrine.com; Investors: Todd Tushla, 1-858-617-7143, ir@neurocrine.com